THE ADHESIVE AND SEALANT COUNCIL, INC.
WHERE THE INDUSTRY MEETS

March 28, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane Rm. 1061
Rockville, MD 20852

Re: Comments on FDA's Proposed Regulation for Prior Notice of Imported Food Under the Public Health Security and Bioterroism Preparedness and Response Act of 2002 [Docket 02N-278]

To Whom It May Concern:

The Adhesive and Sealant Council, Inc. (ASC) is an international trade association representing 125 manufacturers of adhesives and sealants and suppliers of raw materials to the industry. The Council's member companies offer a wide range of adhesive and products utilized by consumer and commercial markets including adhesives utilized by the food packaging industry.

ASC on behalf of its members respectfully submits these comments with regard to the regulation proposed by the U.S. Food and Drug Administration (FDA) entitled "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness Act of 2002," published in the Federal Register on February 3, 2003. (68 Fed. Reg. 5377) FDA's notice of proposed rulemaking requested public comment on the paperwork burden with the implementation of the provision requiring that companies importing food to the U.S. provide FDA with prior notice of each shipment.

The Council commends Congress and the FDA for taking actions to protect the nation's food supply from acts of terrorism and we assure the agency that our members are committed to working with the agency to take all reasonable steps to protect the public food supply. However, in reviewing this proposal we respectfully submit the FDA has mistakenly extended import notification with respect to food-contact materials that is contrary to Congressional intent.

02N-0278 C115

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As background, FDA seeks to bring suppliers of food-contact materials into parameters of the proposal by referring to the definition of 'food" found in Section 201(f) of the Federal Food, Drug, and Cosmetic Act (FFDCA) which defines "food" as (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." 21 U.S.C. § 321(f). Historically, FDA has relied on the FFDCA's definition of "food," in conjunction with its definition of "food additive" to provide a basis for the Agency to assert regulatory authority over any food-contact materials that are also food additives. The FFDCA's language defines in part, "food additive" to include any substance the intended use of which results or may be reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food." 21 U.S.C. §321(s) In the proposed regulation the Agency lists examples of products it considers to be covered by the definition of "food", which includes substances that migrate into food from food packaging and other articles that contact food." It would seem clear from this present language that packaging materials such as adhesives would be included in the proposal.

FDA has attempted to clarify exactly which packaging materials would fall within this description. Their proposal states that substances that migrate into the food from food packaging include "immediate food packaging or components of immediate food packaging that are intended for food. Outer packaging is not considered a substance that migrates into food." The terms immediate food packaging or components of immediate food packaging," could conceivably cover a vast range of products, including plastic resins, glass, paper, metal, rubber and many other products used in food packaging.

ASC members contend the scope of the present language in the proposal with respect to food contact materials is contrary to the intent of Congress as evidenced by the language of the statute itself. With regard to who should be the registering parties, the Bioterrorism Act clearly states that facilities, that "manufacture, process, pack or hold **food for consumption** in the United States" will be required to register (emphasis added). It would be presumable that the term "food for consumption" be properly interpreted as referring to edible food, not food-contact articles.

Finally, it should be noted that in Section 307 of the legislation it states that FDA must receive prior notice of import of each "article of food" that is being imported. Because this wording raised some question of whether packaging materials were intended to be subject to this provision of the legislation, the bill manager in the House of Representatives, Rep. John Shimkus (R-IL) entered in to the *Congressional Record* on May 24, 2002 an extension of his remarks stating:

> Mr. Speaker, in addition to my statement for the record on May 22, 2002 during floor consideration of H.R., 3448, let me clarify that language included in the Conference Report regarding Section 307 as it relates to food packaging materials. Section 307 dealing with prior notice of imported food shipments should not be construed to apply to food packaging materials or other food contact substances, if at the time of importation, they are not used in food.

Clearly it would seem that this statement would reflect the intent of Congress with regard to the entire legislation, not just the prior notification requirements under Section 307.

It should also be noted that by apparently drawing all food packaging materials into the proposal, FDA creates increased uncertainty of what materials are actually included in the regulation. Interpretation of the present language could justifiably extend to all components of the immediate packaging that have the opportunity to migrate into the food. Construal in that manner could extend this regulation to a vast number of companies, many of which would be likely unaware of their products' inclusion.

Theoretically the new regulation would not only apply to facilities manufacturing packaging materials but to warehouses where these products are stored.

ASC members also are concerned that requiring a prior notice of import would have limited usefulness in satisfying the purpose of the Bioterrorism Act which is to "expand FDA's powers to prevent and respond effectively to terrorist threats against the food supply." Manufacturers of adhesives utilized in the food packaging also provide these same products to non-food industry customers. Often they are merely the raw material supplier to various like industries with little knowledge of the specific end-use

of their products. Requiring a prior notice of import simply because their products may be used in a food packaging operation would seem counter productive to FDA's goal of responding quickly to an imminent terrorist threat or attack on the U.S. food supply. Requiring a prior notice of import for adhesive materials, as well as the food contact components of other similarly situated industries, will merely increase the paperwork burden on industry and use valuable FDA resources to review documents and inspect shipments. The value of such a requirement would disproportionate to any minimal reduction in risk and will provide no significant protection against bioterrorism.

In conclusion, it would appear that FDA has misconstrued Congressional intent with regard the prior notice of import for food-contact materials. Additionally, such registrations may only further burden FDA's investigatory efforts to deter and respond to terrorist attacks on the U.S. food supply.

Nevertheless, if FDA continues to propose the inclusion of some food-contact materials within the proposed regulation, the scope of the products covered must be clarified in the final regulation.

If you have any further questions, or need additional information, please do not hesitate to contact me at 301/986-9700 ext. 112.

Sincerely,

Mark Collatz
Director of Government Relations